

### **REMARKS/ARGUMENTS**

This response is made in response to the Office Action dated January 26, 2004.

Therein, the Examiner rejected all of the claims based on either 35 USC § 102 or 35 USC § 103 as anticipated by the Pinchuk reference, U.S. Patent No. 6,545,097. For the reasons described herein this rejection is respectfully traversed. As can be seen from the face of the Pinchuk patent, Pinchuk was filed on December 12, 2000. The present application bears a filing date of May 19, 2000, and is based on a provisional application filed May 12, 2000. Moreover, Applicants can show (if necessary) conception and reduction of practice from a date well before May 12, 2000. Accordingly, Pinchuk is simply not "prior" art to the present application. Any references to Pinchuck should be removed.

Claims 1, 3 and 4 were rejected under 35 USC § 103 as being unpatentable over Ragheb, U.S. Patent No. 6,299,604 in view of Morris, U.S. Patent No. 5,516,781. Claim 5 was rejected in view of Ragheb in view of Morris further in view of the End article. Claims 6 and 7 were rejected under 35 USC § 103 as patentable over Ragheb in view of Morris and further in view of the Levitzki patent, U.S. Patent No. 5,932,580. Claims 8 and 9 were rejected under 35 USC § 103 as being unpatentable over Ragheb in view of Morris and further in view of the Nagler patent, U.S. Patent No. 6,159,488.

The Examiner appropriately recognizes that Ragheb does not describe an anti-proliferative such as rapamycin or any analogue thereof. The Examiner uses the Morris patent to teach the properties of rapamycin. In the Examiner's mind it would be obvious to one with ordinary skill in the art to modify the invention of Ragheb to include rapamycin for the purpose of its qualities as an anti-proliferative.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

Serial No. 09/575,480  
CRD-850

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d, 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 – 2143.03 for decisions pertinent to each of these criteria.

At least two, and possibly three of these criteria are not met. Specifically, there is absolutely no suggestion in Ragheb to modify this reference to combine the teachings of Morris. Without this first seminal step, obviousness is certainly not met. Second, *even if* one were to combine the references, there is no indication from Ragheb that there would be an expectation of success. Ragheb enumerates a “laundry list” of drugs and types of agents. It is impossible for Ragheb to show any reasonable expectation of success, except in the case of the drug heparin, which he uses extensively in his experiments. Therefore, the Examiner has not met the second step of the *prima facie* test of obviousness. Third, while Morris does in fact describe an anti-proliferative, there is no corresponding suggestion of the combined agents in Ragheb.

In this fashion, the Examiner must acknowledge that the claims are patentable over Ragheb in view of the Morris patent, alone or in combination with any of the other teachings.

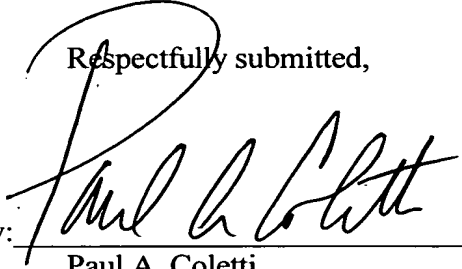
The claims were provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over the claims in co-pending application 09/850,482.

The Applicants understand that this rejection is to alert Applicants that an actual rejection on the same grounds may be issued if one of the applications ultimately issues. However, in light of the amendment to the claims of the present invention and potential amendments made to the claims of the cited application, Applicants will defer any arguments or actions on the claims based on this type of double patenting rejection, until the applications are either allowed or issued as patents.

Serial No. 09/575,480  
CRD-850

Applicants also herewith re-submit the original Information Disclosure Statements, as it appears the examiner has not "checked-off" the citation to these references. If the Examiner needs any of the references re-submitted, the Applicants will do so.

Applicants earnestly solicit a Notice of Allowance in the above captioned application for claims 1 and 3-9.

Respectfully submitted,  
  
By: \_\_\_\_\_  
Paul A. Coletti  
Reg. No. 32,019

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2815  
Dated: April 23, 2004